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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
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09/068,253 06/09/98 SHIMURA

T 146.1286

EXAMINER

HM22/0818

CHARLES A MUSERLIAN  
BIERMAN MUSERLIAN & LUCAS  
600 THIRD AVENUE  
NEW YORK NY 10016

MOEZIE, F

ART UNIT

PAPER NUMBER

1654

8

DATE MAILED:

08/18/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

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## Office Action Summary

Application No.

09/068,253

Applicant(s)

SHIMURA et al

Examiner

Fatemeh Moezie

Group Art Unit

1654

☒ Responsive to communication(s) filed on May 28, 1999

8/18/99

☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-5 and 7-11 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.☒ Claim(s) 1-5 and 7-11 is/are rejected.☐ Claim(s) \_\_\_\_\_ is/are objected to.☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 1☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Applicant's arguments filed 05/28/99, paper no. 7, have been fully considered but they are persuasive-in part.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5 and 7-11 remain rejected under 35 USC 112, second paragraph because: the claims as written are indefinite and confusing.

Claim 1 is confusing and indefinite as to what is being claimed. If a composition is intended to claim the preamble of the claim would have to be separated from the body of the claim by a transition phrase such as comprising or consisting of. The claim as amended lacks the transition phrase, for example.

In claim 3 the terms "a concentration" and "an aqueous", lines 2 and 3, respectively lack basis in claim 2 from which it depends. If an aqueous solution of a bone --- is intended to claim, the preamble of the claim must carry the said language. Furthermore, if the above terms refer to the previous claims, then "the" should precede said terms.

In claims 3, 4 and 5 the term "material" lacks antecedent basis in claims 1 and 2 from which they depend.

In claim 7 the subject being treated does not appear in the preamble of the claim drawn to a method for treating---.

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The rejection of claims 1-5 and 7-11 under 35 USC 103 (a) over RON ~~in~~ et al, WO 93/00050 in view of The Condensed Chemical Dictionary is withdrawn in view of the applicants' remarks.

***NEW GROUND OF REJECTION***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/1483.

The reference discloses a therapeutic material comprising a protein and a hydrophilic polymer as a carrier. See line 4, page 15, for morphogenetic factor and page 10, lines 13-14 for polyoxyethylene-polyoxypropylene copolymer as a component of the composition. In addition the term aqueous solution is defined on page 18, lines 29+. Because claim 1 is drawn to a subject matter taught by the art, the claim is anticipated by the art.

Claims 2-5 and 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/1483 A in view of JP 62-135431 or RON et al.

The primary reference's teachings have been disclosed above. However, the primary reference does not teach a method for treating osteogenetic disorders.

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The secondary references teach the use of bone morphogenetic factors in treating bone disorders. See the entire documents, especially RON et al wherein the most preferred osteogenetic substance is BMP-2, page 3, line 34.

It would have been obvious to an artisan at the time the invention was made to use a bone morphogenetic factor and a hydrophilic polymer of the primary reference for treating bone disorders.

Some of the references cited in the earlier IDS, are missing from the file. The references are the ones cited in the International Search Report. Applicant is requested to submit the missing references to PTO to complete the records. Further, according to the International-Preliminary Examination Report the references cited therein are relevant to the instant case. A second copy of IDS is being forwarded to the applicant.

Any inquiry concerning this communication should be directed to Examiner Moezie at telephone number (703) 305-4508 or Mr. Woodward (SPE) at 308-4028.

*J. J. Moezie*  
F. T. MOEZIE, P.E.  
PRIMARY EXAMINER  
ART UNIT 1654